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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/697,898 | 10/27/2000 | Vito J. Palombella | MPI00- 133M | 5304 |

7590 08/12/2003

Intellectual Property Group
MILLENNIUM PHARMACEUTICALS INC
75 Sidney Street
Cambridge, MA 02139

EXAMINER

SLOBODYANSKY, ELIZABETH

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1652

DATE MAILED: 08/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/697,898

Applicant(s)

PALOMBELLA ET AL.

Examiner

Elizabeth Slobodyansky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The amendment filed May 27, 2003 amending the specification to delete the embedded hyperlink, canceling claims 27-52 and adding claims 53-60 has been entered.

The statement regarding the biological deposit is given on pages 15-16 of Remarks.

Claims 53-60 are pending.

Specification

The specification describes SEQ ID NO:3 (1-4539 nucleotides) as the coding region of SEQ ID NO:1, nucleotides 7-4545 (page 21, lines 25-27). However, while in the Sequence Listing SEQ ID NO:1 is a nucleotide sequence of 5245 nucleotides, SEQ ID NO: 3 is an amino acid sequence of 1495 amino acid residues. SEQ ID NO:3 is 96% identical to SEQ ID NO:2 of the instant invention. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 53-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53-60 recite "the nucleotide sequence of SEQ ID NO:3" wherein SEQ ID NO:3 is an amino acid sequence.

Claims 53 (h), claim 56(h) and claim 57(h) recite "a sequence, an amino acid sequence" rendering the claims confusing because the sequence is an amino acid sequence. It is unclear whether any other sequence is encompassed.

Amending the claims to delete "a sequence" would obviate this part of the rejection.

Claim 60 is confusing as reciting "a MEKK1 polypeptide selected from the group consisting of a. [] and b. []" wherein "a" and "b" are methods steps.

Claims not specifically rejected herein, are rejected as dependent from a rejected base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 53-59 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Xia et al.

Claim 53 (d), claim 56(d) and claim 57(d) recite a nucleic acid which has at least about 90% sequence identity with SEQ ID NO:1 or SEQ ID NO:3.

Claim 53 (l), claim 56(l) and claim 57(l) recite a nucleic acid encoding MEKK1 sequence having at least about 97% identity to SEQ ID NO:2.

Xia et al. teach a nucleic acid encoding MEKK1. Further, Xia et al. teach a vector and a host cell comprising said nucleic acid sequence (pages 3378-3379, Materials and methods). Said sequence has "Query match" of 87% with SEQ ID NO:1 of the instant invention. The "best local similarity" between the two sequences is 99.0%.

The nucleic acid sequence taught by Xia et al. encodes a MEKK1 amino acid sequence that has "Query match" of 96% with SEQ ID NO:2. The "best local similarity" between the two sequences is 97.8%.

The claims recite percent identity as "**about**" 90% or 97%. Therefore, the Xia et al. reference anticipates claims 53-59.

However, even without the "about" limitation, the claims are anticipated by Xia et al. because sequences can be compared in different ways. Percent identity depends on algorithms and parameters that are used for calculating the identity. Without

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precisely knowing said algorithms and parameters, it is impossible to distinguish between the sequences taught by Xia et al. and the claimed sequences.

Furthermore, the nucleic acid sequence taught by Xia et al. is 100% identical to the nucleic acid sequence encoding SEQ ID NO:3 of the instant invention. Because of this, claim 60 is also included in this rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Monia et al. (US Patent 6,168,950) teach a nucleic acid of SEQ ID NO:1 (column 39, lines 30-34, SEQ ID NO:1) that is the sequence disclosed by Xia et al. (GenBank accession AF042838).

Response to Arguments

Applicant's arguments filed May 27, 2003 relate to the rejections that are moot in view of the amendment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, reading "E. Slobodyansky". The signature is written in black ink and is positioned above the printed name and title.

Elizabeth Slobodyansky, PhD
Primary Examiner

August 8, 2003